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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,984	07/01/2002	Thomas Frank Bumol	X-13199	3218

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EXAMINER	
GALVEZ, JAMES JASON	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 01/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,984	BUMOL ET AL.	
	Examiner	Art Unit	
	J. Jason Galvez	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) *4-7* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 8-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/1/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I in the reply filed on 11/05/2004 is acknowledged. Claims 1-12 are pending in this application. Claims 4-7 are directed to non-elected subject matter. Claims examined are claims 1-3 and 8-12.

Specification

The use of the trademarks SUPERSCRIPT (p. 20), KAMIYA BIOMEDICAL (p. 23 and 25), KODAK (p. 24), BIO-RAD (p. 24), and BECTON DICKINSON (p. 25), have been noted in this application. Trademarks should be capitalized wherever they appear and should be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 9, and 11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of reducing apoptosis by

administering FLINT polypeptides, does not reasonably provide enablement for a method of inhibiting any and all lung diseases by administering FLINT polypeptides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. It is noted that the recitation of "inhibiting" or "inhibition" encompasses both treatment and prevention, the later of which is not enabled by the instant disclosure.

The factors to be considered when determining if the disclosure satisfies the enablement requirement have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breath of claims. *Ex Parte Forman*, (230 USPQ 546 (Bd. Pat. App. & Int. 1986)); *In re Wands*, 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

Claims 1-3, 9, and 11 are directed to polypeptides and a method of inhibiting lung diseases. "Inhibition" of certain diseases based on some intervention is an issue and is especially difficult to establish because to do so Applicant must be able to provide some evidence that the pathological condition is predicable and that the intervention was able to inhibit the pathological state, which has not been established in the instant disclosure. For example, the specification states the pulmonary fibrosis is "an end result of the process of attempted healing during acute or chronic lung injury" (p. 10: lines 11-12).

Therefore, pulmonary fibrosis could initially present itself following a car accident, a scenario that cannot be predicted and shown to be inhibited by the instant invention.

Claim 1 requires that the molecule be useful to treat "a lung disease". "Lung disease" is interpreted as meaning all lung diseases. Lung diseases, as interpreted, encompass many pathological conditions ranging from asthma to sudden acute respiratory syndrome (SARS). Absent any evidence that the claimed invention would have use directed against any and all lung diseases a person of ordinary skill in the art would not be able to predict its use under the broad scope of the claim.

For the reasons stated above, a person of ordinary skill in the art cannot practice the invention commensurate in scope with the claims due to the quantity of experimentation necessary, the absence of working examples, the nature of the invention, and the breadth of the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3 and 12 rejected under 35 U.S.C. 102(b) as being anticipated by Ashkenazi (US Patent Application Publication 2002/0065210 [effective filing date: 7-

98]). Ashkenazi et al. disclose a polypeptide, designated "DcR3", that has 100% sequence identity to claimed "FLINT" polypeptides. The intended use of the claimed molecules does not change the patentability of the molecules. Thus Ashkenazi et al. meet the limitations of claims 1-3. Additionally, Ashkenazi et al. teach that "DcR3" can inhibit T-cell activation resulting in decreased cell death (p. 18: [0240], p. 19: [0244], and Figure 9: B-C). Thus, Ashkenazi et al. meet the limitations of claim 12.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ashkenazi et al. (Pub No.: US 2002/0065210 A1 [effective filing date 9/98]) in view of Hagimoto et al. (Am J Respir Cell Mol Biol. 1997, Vol. 16(1): pp. 91-101, esp. Figures 3-4). Ashkenazi et al. teach a molecule, designated "DcR3", that inhibits binding between FasL-Fas receptor (p. 5: [0064]). Ashkenazi et al. however, do not teach a method of using "DcR3" to treat pulmonary fibrosis.

Hagimoto et al. teach increased apoptosis and increased mRNA levels of FasL/Fas mediate pulmonary fibrosis (pp. 98-99: Figures 3-4).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use the FasL-Fas receptor inhibitory molecule "DcR3" in a

method directed to treating pulmonary fibrosis. Additionally, a person of ordinary skill in the art would have been motivated to incorporate the teachings of Ashkenazi et al. and Hagimoto et al. because pulmonary fibrosis can result in a decreased life span due to the inability of the body to adequately management gas exchange across the lung surface. In some cases the mean survival after diagnosis is less than 5 years (Khalil et al. CMAJ 2004, Vol. 171(2): pp. 153-160, esp. p. 153: column 1, paragraph 3). Furthermore, the expectation of success is reasonably assured based on the teachings of Ashkenazi et al. where it was experimentally shown that "DcR3" can bind to FasL and decrease cell death (Figure 8-9).

Claims 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ashkenazi et al. (Pub No.: US 2002/0065210 A1 [effective filing date 7/98]) in view of Hagimoto et al. (Am J Respir Cell Mol Biol. 1997, Vol. 17(3): pp. 272-278, esp. p. 277). Ashkenazi et al. teach a molecule, designated "DcR3", that inhibits binding between FasL-Fas receptor (p. 5: [0064]). Ashkenazi et al. however, do not teach a method of using "DcR3" to treat pulmonary fibrosis.

Hagimoto et al. teach FasL-Fas mediate pulmonary fibrosis (p. 277: column 1, paragraph 2).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use the FasL-Fas receptor inhibitory molecule "DcR3" in a method directed to treating pulmonary fibrosis. Additionally, a person of ordinary skill in the art would have been motivated to incorporate the teachings of Ashkenazi et al. and Hagimoto et al. because pulmonary fibrosis can result in a decreased life span due to

the inability of the body to adequately management gas exchange across the lung surface. In some cases the mean survival after diagnosis is less than 5 years (Khalil et al. CMAJ 2004, Vol. 171(2): pp. 153-160, esp. p. 153: column 1, paragraph 3). Furthermore, the expectation of success is reasonably assured based on the teachings of Ashkenazi et al. where it was experimentally shown that "DcR3" can bind to FasL and decrease cell death (Figure 8-9).

Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ashkenazi et al. (Pub No.: US 2002/0065210 A1 [effective filing date 7/98]) in view of Yamamoto et al. (Chest. 1997, Vol. 112(2): pp. 505-510, esp. p. 508: Figure 3) and Hebestreit et al. (Eur J Immunol. 1996, Vol. 26(8): pp. 1775-1780). Ashkenazi et al. teach a molecule, designated "DcR3", that inhibits binding between FasL-Fas receptor (p. 5: [0064]). Ashkenazi et al. however, do not teach a method of using "DcR3" to treat chronic obstructive pulmonary disease (COPD).

Yamamoto et al. teach that elevated markers of eosinophils, i.e. increased eosinophils, accompany COPD (p. 508: Figure 3). Hebestreit et al. teach that eosinophils express Fas receptor and can mediate increased apoptotic cell death (p. 1777-1778: Figure 2-3).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use the FasL-Fas receptor inhibitory molecule "DcR3" in a method directed to COPD. Additionally, a person of ordinary skill in the art would have been motivated to incorporate the teachings of Ashkenazi et al., Yamamoto et al., and Hebestreit et al. because COPD is emerging worldwide as one of the leading causes of

morbidity and mortality (Groneberg et al., Respir Res. 200, Vol. 5(1): pp. 18-34, esp. p. 18: column 1, paragraph 1). Furthermore, the expectation of success is reasonably assured based on the teachings of Ashkenazi et al. where it was experimentally shown that "DcR3" can bind to FasL and decrease cell death (Figure 8-9).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **J. Jason Galvez, Ph.D**. whose telephone number is **571-272-2935**. The examiner can normally be reached Monday through Friday 9 AM to 5 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback, Ph.D.** can be reached at **571-272-0887**.

The fax phone number for the organization where this application or proceeding is assigned is **703-872-9306**. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

JJG
1/05/2004

JANET ANDRES
PRIMARY EXAMINER